UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): September 29, 2020

CTI BIOPHARMA CORP.
(Exact name of registrant as specified in its charter)

Delaware	**000-28386**	**91-1533912**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**

3101 Western Avenue, Suite 800
Seattle, Washington 98121
(Address of Principal Executive Offices, and Zip Code)

(206) 282-7100
(Registrant's Telephone Number, Including Area Code)

Not applicable
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communication pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communication pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communication pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.001 per share	**CTIC**	**The Nasdaq Capital Market**

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 8.01 Other Events.

On September 29, 2020, CTI BioPharma Corp. (the "Company") issued a press release announcing the Company's plans to submit a new drug application seeking FDA approval of pacritinib for the treatment of myelofibrosis patients with severe thrombocytopenia. A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated by reference herein.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit	Description
99.1	Press release dated September 29, 2020
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

September 29, 2020

CTI BioPharma Corp.

By: /s/ David H. Kirske
David H. Kirske
Chief Financial Officer

CTI BioPharma to Submit a New Drug Application (NDA) for the Accelerated Approval of Pacritinib for the Treatment of Myelofibrosis Patients with Severe Thrombocytopenia

– Company to Proceed with Rolling NDA Submission following Recent Pre-NDA Meeting with FDA –

– Rolling NDA Expected to Commence in the Fourth Quarter of 2020 –

– Completion of NDA Submission Expected in First Quarter 2021 –

– Company to Host Conference Call on Wednesday, September 30 at 8:30 AM ET –

SEATTLE, Sep. 29, 2020 - CTI BioPharma Corp. (Nasdaq: CTIC) today announced that following a recent Pre-NDA meeting with the U.S. Food and Drug Administration ("FDA" or "the Agency"), the Company has reached an agreement to submit an NDA for the potential accelerated approval of pacritinib as a treatment for myelofibrosis patients with severe thrombocytopenia (platelet count less than 50 x 10^9/L). The NDA will be based on the available data from the Company's completed Phase 3 PERSIST-1 and PERSIST-2 trials and the Phase 2 PAC203 dose-ranging trial. The FDA has agreed to a rolling NDA submission which is expected to commence within a few weeks, with completion of the NDA submission anticipated in the first quarter of 2021. The ongoing Phase 3 PACIFICA trial is expected to be completed as a post-marketing commitment.

"Since the completion of the PAC203 Phase 2 dose-ranging trial, we have been working collaboratively with the FDA to identify an expeditious approval pathway for pacritinib in myelofibrosis patients with severe thrombocytopenia, a patient population with an important unmet medical need due to reduced survival and limited therapeutic options. During a recent Pre-NDA meeting, we identified a data package from the PERSIST-1, PERSIST-2 and PAC203 Phase 2 trials that will serve as the basis for an accelerated approval application. In particular, we discussed risk mitigation measures to address the FDA's prior concerns regarding safety," said Adam R. Craig, M.D., Ph.D., President and Chief Executive Officer of CTI Biopharma. "In myelofibrosis patients, severe thrombocytopenia occurs as a result of disease or drug-related toxicity from current therapies. There is no approved

drug that specifically addresses the unmet need of the myelofibrosis patients who have severe thrombocytopenia. Pacritinib has demonstrated clinical benefit in treating these patients in multiple trials and now has the potential to become a new treatment option for treatment-naïve and second-line myelofibrosis patients in 2021."

Conference Call and Webcast

CTI will host a conference call and webcast to discuss this announcement tomorrow, September 30, 2020 at 8:30 AM ET. To access the live call by phone please dial (877) 735-2860 (domestic) or (602) 563-8791 (international); the conference ID is 9275344. A live audio webcast of the event may also be accessed through the "Investors" section of CTI's website at www.ctibiopharma.com. A replay of the webcast will be available for 30 days following the event.

About Myelofibrosis and Severe Thrombocytopenia

Myelofibrosis is a type of bone marrow cancer that results in formation of fibrous scar tissue and can lead to severe anemia, weakness, fatigue and an enlarged spleen and liver. Patients with severe thrombocytopenia are estimated to make up more than one-third of patients treated for myelofibrosis, or approximately 17,000 people. Severe thrombocytopenia, defined as blood platelet counts of less than 50,000 per microliter, has been shown to result in overall survival rates of just 15 months. Thrombocytopenia in patients with myelofibrosis is associated with the underlying disease but has also been shown to correlate with treatment with ruxolitinib, which can lead to dose reductions, and as a result, may potentially reduce clinical benefit. Survival in patients who have discontinued ruxolitinib therapy is further compromised, with an average overall survival of seven to 14 months. Myelofibrosis patients with severe thrombocytopenia have limited treatment options, creating a significant area of unmet medical need.

About Pacritinib

Pacritinib is an investigational oral kinase inhibitor with specificity for JAK2, FLT3, IRAK1 and CSF1R. The JAK family of enzymes is a central component in signal transduction pathways, which are critical to normal blood cell growth and development, as well as inflammatory cytokine expression and immune responses. Mutations in these

kinases have been shown to be directly related to the development of a variety of blood-related cancers, including myeloproliferative neoplasms, leukemia and lymphoma. In addition to myelofibrosis, the kinase profile of pacritinib suggests its potential therapeutic utility in conditions such as acute myeloid leukemia (AML), myelodysplastic syndrome (MDS), chronic myelomonocytic leukemia (CMML), and chronic lymphocytic leukemia (CLL), due to its inhibition of c-fms, IRAK1, JAK2 and FLT3.

In March 2008, pacritinib received orphan drug designation for the treatment of primary myelofibrosis (MF), post-polycythemia vera MF, and post-essential thrombocythemia MF.

In August 2014, pacritinib was granted Fast Track designation by the FDA for the treatment of intermediate and high risk myelofibrosis, including, but not limited to, patients with disease-related thrombocytopenia (low platelet counts); patients experiencing treatment-emergent thrombocytopenia on other JAK2 inhibitor therapy; or patients who are intolerant of or whose symptoms are not well controlled (sub-optimally managed) on other JAK2 therapy.

About CTI BioPharma Corp.

We are a biopharmaceutical company focused on the acquisition, development and commercialization of novel targeted therapies for blood-related cancers that offer a unique benefit to patients and their healthcare providers. We concentrate our efforts on treatments that target blood-related cancers where there is an unmet medical need. In particular, we are focused on evaluating pacritinib, our sole product candidate currently in active development, for the treatment of adult patients with myelofibrosis. In addition, we have recently started developing pacritinib for use in hospitalized patients with severe COVID-19, in response to the COVID-19 pandemic. We are headquartered in Seattle, Washington.

Forward-Looking Statements

Statements included in this press release that are not historical in nature are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934 and the Private Securities Litigation Reform Act of 1995. These forward-looking statements are based on current assumptions that involve risks, uncertainties and other factors that may cause the actual results, events or

developments to be materially different from those expressed or implied by such forward-looking statements. These risks and uncertainties include, but are not limited to: our ability to conduct and complete clinical trials in our currently anticipated timeframes; our ability to successfully demonstrate the safety and efficacy of pacritinib; our expectations regarding the completion and outcome of our PACIFICA Phase 3 trial and our PRE-VENT Phase 3 trial; the risk that the FDA may determine that the benefit/risk profile of pacritinib at the dose selected for the PACIFICA Phase 3 trial does not support approval; the risk that the FDA may determine that the benefit/risk profile of pacritinib in the PRE-VENT Phase 3 trial does not support approval or requires additional clinical data for approval; the risk that pacritinib may fail in its development through our PACIFICA and PRE-VENT trial; our ability to submit a rolling NDA for pacritinib in the timeline currently anticipated; our ability to receive regulatory approval for pacritinib pursuant to the accelerated approval pathway or at all; the risk that pacritinib may be delayed to a point where it is not commercially viable; and those risks more fully discussed in the section entitled “Risk Factors” in our Annual Report on Form 10-K for the year ended December 31, 2019 and subsequent quarterly reports on Form 10-Q. These forward-looking statements speak only as of the date hereof and we assume no obligation to update these forward-looking statements, and readers are cautioned not to place undue reliance on such forward-looking statements. “CTI BioPharma” and the CTI BioPharma logo are registered trademarks or trademarks of CTI BioPharma Corp. in various jurisdictions. All other trademarks belong to their respective owner.

CTI BioPharma Investor Contacts:

Maeve Conneighton/Maghan Meyers
+212-600-1902
cti@argotpartners.com